

NEW HAMPSHIRE DEPARTMENT OF HEALTH AND HUMAN SERVICES

PROTOCOL DEVIATION/ELIGIBILITY EXCEPTION FORM

Please send to: NH CPHS 1555 Elm St. Manchester, NH 03101

PLEASE TYPE

PRINCIPAL INVESTIGATOR: _____ **PHONE:** _____

INSTITUTION / COMMUNITY PROGRAM _____

E-MAIL _____

CO- INVESTIGATOR: _____ **PHONE:** _____

INSTITUTION / COMMUNITY PROGRAM _____

E-MAIL _____

COORDINATOR: _____ **PHONE:** _____

ADDRESS: _____ E-MAIL: _____

STUDY TITLE: _____ **CPHS #** _____

FUNDING SOURCE(S): _____

The PI shall communicate (via e-mail or mail) a "Request for a Protocol Deviation/ Eligibility Exception" to the CPHS Administrator. The communication shall contain all of the following:

1. CPHS Project # and study title
2. PI name
3. Description of proposed deviation (specific and complete)
4. Rationale for deviation and risk analysis, including, but not limited to:
 - a. What are/were the circumstances which led to a deviation.
 - b. What effect on subject's risk level did/does this deviation have.
- c. Why did the original eligibility criteria exclude subjects in these circumstances (if applicable).
- d. What corrective action has been/will be taken to reduce the likelihood that this deviation will reoccur?
- e. Provide a schedule of monitoring the corrective action described in d.
- f. What effect, if any, will the corrective action have on the level of risk to which the subject is exposed?
5. Explain why the protocol should not be revised to address this subject population.
6. Evidence of sponsor notification and or approval (if applicable)
7. Proposed enrollment date.

The Administrator will forward a copy of the protocol, as needed, to the Chairperson. The Chairperson will then review the request in an expeditious manner, consulting with scientific committee members as necessary, to determine if an exception should be accepted. The IRB response will be returned via e-mail. The response may be accepted as submitted or further follow requested.